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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/676,107	10/02/2003	Noboru Horiguchi		8381

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EXAMINER	
WALLENHORST, MAUREEN	

ART UNIT	PAPER NUMBER
1743	

DATE MAILED: 12/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/676,107	HORIGUCHI ET AL.	
	Examiner	Art Unit	
	Maureen M. Wallenhorst	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-10 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-10 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 3/9/04.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

On line 23 of claim 1, the phrase "factor selected from a " should be changed to –factor selected from the group consisting of—in order to use proper Markush language. This same change should also be made on line 3 of claim 9.

On line 2 of claim 2, the phrase "the venous blood sample" lacks antecedent basis since part (a) of claim 1 recites a "mammalian blood sample".

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over GB Patent no. 996,089 in view of Barrett-Reis et al (US Patent no. 7,090,862).

GB Patent no. 996,089 teaches of a blood test method wherein erythrocytes (i.e. red blood cells) are separated from a blood sample and stored. In the process of storing the erythrocytes, metabolic products are produced intracellularly inside of the red blood cells. The GB patent teaches of a method for measuring these intracellular metabolic products such as lactic acid. The method comprises removing a portion of the metabolic products (i.e. lactic acid) from the erythrocytes during storage by diffusion through the cell wall of the erythrocytes. This is achieved by placing the erythrocytes into a suspension medium such as buffered saline that creates a high diffusion gradient between the interior of the erythrocytes and the suspension medium. The buffered saline solution that creates the diffusion gradient is inherently a hypertonic solution that causes a pressure differential resulting in the flow of intracellular metabolic solutes such as lactic acid from the inside of the erythrocytes to the surrounding saline suspension medium. Figure 3 in the GB patent depicts a graph of the percentage of the products of metabolism (i.e. lactic acid) within the erythrocytes in contrast to the extracellular phase versus the temperature of the erythrocytes in the suspension medium. As depicted in Figure 3,

the graph shows that at temperatures in the range of 25-40°C, there is more lactic acid in the extracellular phase than located within the erythrocytes. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to maintain the erythrocytes in the suspension medium taught by the GB patent in a temperature range of 25-40oC since Figure 3 of the GB patent depicts that this temperature range promotes the diffusion of metabolic products such as lactic acid from the interior of the erythrocytes to the exterior, extracellular suspension medium, thus helping to eliminate the deleterious affects caused by these metabolic products. The GB patent fails to teach the steps by which the erythrocytes are separated from a whole blood sample, and fails to teach how the metabolic products separated from the interior of the erythrocytes by the diffusion gradient are separated from the suspension medium to be measured.

Barrett-Reis et al teach of a method for isolating red blood cells from a whole blood sample. In the method set forth in lines 10-25 of column 35 in Barrett-Reis et al, a blood sample is drawn into a container having EDTA anticoagulant therein and centrifuged. Plasma is removed from the blood cells, and thereafter, the buffy coat (i.e. white blood cells and platelets) is also removed from the remaining red blood cells by centrifugation. The red blood cells in the pellet are washed with phosphate buffered saline (PBS), and resuspended in PBS buffer to give a 50% suspension. Barrett-Reis et al teach that intracellular solutes such as vitamin E can be measured in the resulting isolated red blood cells.

Based upon the combination of the GB patent and Barrett-Reis et al, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to separate the erythrocytes from a whole blood sample in the blood test method taught by the GB patent used

for isolating intracellular solutes therefrom by the series of centrifugation, washing and resuspension steps taught by Barrett-Reis et al since the GB patent discloses that a separated erythrocyte sediment is used in the method to store and isolate intracellular solutes, and a common method for obtaining a separated erythrocyte sediment is to use the centrifugation, washing and resuspension steps disclosed by Barrett-Reis et al. It also would have been obvious to one of ordinary skill in the art to use centrifugation to separate the metabolic products taught by the GB patent that are diffused into the extracellular suspension medium since centrifugation is one commonly used separation technique for isolating one chemical component from another, thus allowing the separate quantitative and qualitative analysis of each component. It also would have been obvious to one of ordinary skill in the art to vary the centrifugation duration times and speeds as well as the temperatures for incubating the red blood cells with the suspension medium taught by the GB patent, in accordance with the parameters set forth in claims 2-8, since such parameters are result effective that can be experimentally varied in order to optimize the separation of the erythrocytes from a whole blood sample and the separation of the intracellular solutes from the erythrocytes. With regards to claim 10, it would have been obvious to one of ordinary skill in the art to measure the oxidation-reduction potential of the intracellular volume of the erythrocytes taught by the GB patent using a well-known potentiometer since the oxidation-reduction potential on the inside of the erythrocytes will change depending on the intracellular production of the metabolic products therein, such as lactic acid.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen M. Wallenhorst whose telephone number is 571-272-1266. The examiner can normally be reached on Monday-Thursday from 6:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maureen M. Wallenhorst
Primary Examiner
Art Unit 1743

mmw

December 4, 2006

Maureen M. Wallenhorst
MAUREEN M. WALLENHORST
PRIMARY EXAMINER
GROUP [redacted] 1700